

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

No. 7:12-CV-00023-F

PHILLIP J. SINGER, Individually and on
Behalf of All Other Persons Similarly
Situated,)
Plaintiff,)
v.)
TRANS1, INC., KENNETH REALI,
JOSEPH P. SLATTERY, RICHARD
RANDALL, and MICHAEL
LUETKEMEYER,)
Defendants.)

ORDER

TRANS1, INC., KENNETH REALI,
JOSEPH P. SLATTERY, RICHARD
RANDALL, and MICHAEL
LUETKEMEYER,
Defendants.

This matter is before the court on the defendants' Motion to Dismiss Plaintiff's Second Amended Complaint [DE-63] pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6).¹ The matter has been fully briefed and is ripe for ruling. For the reasons stated herein, the motion is ALLOWED.²

¹ The defendants have additionally filed a Request for Judicial Notice [DE-60]. The plaintiff has not objected to the motion. Under Rule 201 of the Federal Rules of Evidence, courts may “take judicial notice if a party requests it and the court is supplied with the necessary information.” Fed. R. Evid. 201(c)(2). Courts may take judicial notice of facts that are not “subject to reasonable dispute because [they] . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b)(2). Furthermore, courts ruling on a 12(b)(6) motion to dismiss “may look to ‘documents or articles cited in the complaint, SEC filings, press releases, stock price tables, and other material on which the plaintiff’s allegations necessarily rely.’” *Greenhouse v. MCG Capital Corp.*, 392 F.3d 650, 656-67 (4th Cir. 2004) (quoting *Morris v. Wachovia Sec., Inc.*, 277 F. Supp. 2d 622, 629 (E.D. Va. 2003)). The documents submitted with the Request for Judicial Notice meet this criteria. Therefore, the Request for Judicial Notice [DE-60] is ALLOWED.

² This matter had been stayed pursuant to the court's Order of November 20, 2014 [DE-69]. The issues of that order have been resolved. Therefore, the court hereby LIFTS the stay entered on November 20, 2014.

I. PROCEDURAL AND FACTUAL BACKGROUND

Joel Caplin initiated this action on January 24, 2012, by filing a Class Action Complaint [DE-1] alleging claims for violations of the federal securities laws. On April 2, 2012, Phillip J. Singer moved for appointment as lead plaintiff [DE-21], which the court granted on May 8, 2012 [DE-27].³ On July 11, 2012, Singer filed an Amended Class Action Complaint [DE-29].

In its Order of September 19, 2013 [DE-48], the court dismissed Singer's Amended Class Action Complaint with prejudice. However, on October 17, 2013, the court granted Singer's Motion to Alter or Amend the Order and Judgment of Dismissal with Prejudice [DE-50]. Singer then filed a Second Amended Class Action Complaint ("SAC") [DE-55]. TranS1, Inc., and the individual defendants—who were TranS1 executives during the relevant time period—have now moved to dismiss the SAC.⁴

The court has previously reviewed the facts of this case in great detail. *See* Order of May 5, 2014 [DE-54]; Order of September 19, 2013 [DE-48]. However, given the present motion to dismiss, the court highlights certain allegations from the SAC. Those allegations, which the court must accept as true for purposes of this motion, show the following.

TranS1 is a publicly-traded medical device company that designs, markets, and sells medical devices used in spinal procedures. *See* SAC [DE-55] ¶ 2. Its primary product and main source of revenue is the AxiaLIF line of products. *See id.* ¶¶ 2-3. AxiaLIF generates revenue when surgeons use it during patient surgeries and then seeking reimbursement. *Id.* ¶ 4. Surgeons will only purchase AxiaLIF as long as insurance companies reimburse them for AxiaLIF. *Id.*

³ In its Order of November 20, 2014 [DE-69], the court inadvertently referred to Joel Caplin as the lead plaintiff in the case caption. Singer is now the lead plaintiff in this matter.

⁴ TranS1, shortly after moving to dismiss the Second Amended Complaint, entered a notice of its bankruptcy filing [DE-68], resulting in an automatic stay of these proceedings as to TranS1. Therefore, the court considers the present motion to dismiss only as to the individual defendants: Reali, Slattery, Randall, and Luetkemeyer.

When submitting for reimbursement, surgeons must label their procedures with codes, known as Current Procedural Terminology (“CPT”) codes. *Id.* The American Medical Association (“AMA”) issues the CPT codes and generally adopts those codes from recommendations made by the National Association of Spine Surgeons (“NAS”). *Id.*

In 2008, NAS concluded that AxiaLIF was not an anterior procedure, as it had previously been coded. *Id.* ¶ 5. Based on the NAS’s conclusion, the AMA changed AxiaLIF’s CPT code to a Category III code effective January 2009. *Id.* The change classified AxiaLIF as an experimental procedure. *Id.* Insurance companies generally do not reimburse surgeons performing procedures with a Category III CPT code. *Id.* ¶ 6.

The plaintiff alleges that, due to the negative financial implications of the Category III code classification for AxiaLIF, the defendants “embarked on a campaign to encourage surgeons to disregard the Category III code and employ alternate, wholly inapplicable, CPT codes to receive reimbursement.” *Id.* ¶ 7.⁵ Specifically, the SAC alleges that the defendants did the following:

- (1) form[ed] a reimbursement committee to “coach” surgeons on how to avoid using the assigned Category III CPT code and utilize an inapplicable CPT code meant for anterior procedures;
- (2) [held] conference calls with distributors during which they were trained on how to convince surgeons to use the CPT code for anterior procedures rather than the mandatory Category III code;
- (3) creat[ed] a template setting forth specific steps surgeons should take to avoid using the assigned Category III coding and fraudulently obtain reimbursement;
- (4) draft[ed] and dispers[ed] a Reimbursement Guide setting forth alternate codes to use in place of the mandatory Category III code;

⁵ Incorporated into the SAC’s allegations are references to a *qui tam* complaint brought by a former TranS1 sales manager. *See id.* ¶ 39. On June 28, 2013, TranS1 entered into a settlement agreement with the government regarding the *qui tam* complaint. *Id.* ¶ 46; *see also* Settlement Agreement [DE-46-1] at 19. In the settlement agreement, TranS1 expressly denied the allegations of the *qui tam* complaint and did not admit liability. *See* Settlement Agreement [DE-46-1] at 3, ¶ E.

- (5) promot[ed] the use of the anterior CPT code rather than the assigned Category III code at the Company's National Meeting held in January 2009, attended by Defendant Randall; and
- (6) knowingly misrepresent[ed] AxiaLIF as having been "approved for marketing" by the FDA for non-adjunct to fusion use in spinal fusion surgeries.⁶

Id. The court now considers these allegation categories in turn.

a. Reimbursement Committee

The "Defendants formed a reimbursement committee" intended to train surgeons on how to avoid using the Category III CPT code. *Id.* ¶ 32. This committee, headed by Amy Conners,⁷ and under the "Defendants' direction . . . drafted presentations for surgeons detailing exactly which non-experimental codes to use, and in what manner, so that insurance companies would reimburse them for the AxiaLIF procedure." *Id.* During these presentations, Conners would show "surgeons how to input the numbers in a certain order to ensure reimbursement for the procedure." *Id.* ¶ 51. Conners's presentation would not teach surgeons to omit the Category III CPT code, but rather how to "bury" the code in the "bottom part of the reimbursement request so that insurance companies might overlook it." *Id.* ¶¶ 51, 54. Conners also made presentations to TranS1's board about reimbursement issues. *Id.* ¶ 51. Finally, Conners created a hotline that surgeons could call for tips on how to code the procedure. *Id.*

⁶ The SAC contains a single allegation supporting this point, which was incorporated from the *qui tam* complaint. *See id.* ¶ 40 ("The *qui tam* Complaint alleges that Defendants, by promoting use of improper CPT codes to bill for AxiaLIF, misrepresented to physicians and hospitals that the FDA had approved AxiaLIF as similar to reimbursable 'anterior stabilization and fusion procedures' without clarifying that it must be performed as an 'adjunct to posterior fusion and instrumentation[,'] which would not be reimbursed by insurers.").

⁷ The SAC also refers to Conners as "Conner" or "Connors." For consistency, the court will use the first-mentioned name, Conners, except where included in a specific quote with a different spelling.

b. Conference Calls

TranS1 held “periodic conference calls with distributors about coding and told distributors what to tell surgeons about coding.” *Id.* ¶ 56. During these calls, “Trans1 told distributors to use an ‘ALIF’ code, despite the fact that [AxiaLIF] did not qualify as an anterior procedure.” *Id.* When some surgeons expressed concerns, “distributors were supposed to tell them: ‘We have seen other surgeons use this code and be successful.’” *Id.* ¶ 57.

In a conference call held on February 23, 2009, the SAC alleges that Defendants Randall and Luetkemeyer made the following statements:

Defendant Randall: On the reimbursement front, we remain diligent about helping our surgeons obtain appropriate reimbursement for our procedure. We have an 800 number and a call-in resource center up and running to assist surgeons with reimbursement issues that may arise.

As many of you know, a portion of our surgeon fee migrated from an unlisted code to a category three CPT tracking code in January 2009. While we remain focused on supporting our surgeons through this transition, we do not anticipate that this will create any significant additional headwind with regards to adoption.

Defendant Luetkemeyer: Doug, what we said in the script was that the conversion from unlisted to category three, we didn’t see giving us any significant additional headwind. I think the metric that we’ve provided in the past is that we feel, and it’s hard to really quantify it, but we feel that unlisted code gave us about a 5% kind of headwind and it’s probably consistent again this year. We don’t feel that moving from unlisted to category three is going to provide any significant additional headwind.

Id. ¶ 69. In another conference call on April 27, 2009, Defendant Randall stated that

[o]n the reimbursement front, we remain diligent about helping our surgeons obtain appropriate reimbursement for our procedure. We have an 800 number and call-in resource center, up and running to assist surgeons with reimbursement issues that may arise.

We have also added two additional reimbursement specialists in the field to work with our surgeon customers and their billing specialists, to help them determine the appropriate coding for the fusion procedures they are performing.

As a strong case volume this quarter would suggest, we have not seen a drop off in procedure volumes as a result of the current weak economic conditions. Having said that, we have begun to see some insurance companies raising the bar on whether to pay for fusion surgery in general or asking more patients to get a second opinion, before agreeing to cover the procedure.

[W]e had the category-three code put in place in January and that was a change in coding. We have actually put out a coding guide now, which has been blessed by everyone. And coding fusions is fairly complex and what we saw initially with the category-three code was right away a lot of coders in the practice went to the concern that like the Charité disc they are just not going to get paid.

The reality is, as we've discussed in the past, this access code is one of several codes that they employ during a typical fusion. So I would say our coding issues have been grassfires, not forest fires, and so, this flare is up. A coder becomes concerned, because they see a category-three code. And we either work through the rep, or we work through the hotline, or now we've actually, as I have mentioned, brought on a couple of field related personnel, who had worked . . . where they knew category-three code inside and out. Those people are then, if needed, deployed and we put these fires out.

I don't think we've had many instances, if any, where we just have surgeons stop doing this, but often times there is a concern when they see the category-three code. We need to work with them and once they understand the coding sequence, based on the particular operation that the surgeon does, we move through the process. So, that's why we proactively hired these folks. And now, the plan going forward is as we bring in new surgeon on by having field base, personnel to deal with this matter. We can actually have those personnel meet with the coders before the surgeon even treats patients with AxiaLIF, so that we don't even have the little flash fire to deal with.

Id. ¶ 74.

On May 24, 2010, a conference call was held during which Defendants Slattery and Reali discussed "headwind" caused by the experimental designation. *Id.* ¶ 88. Reali spoke directly about working to remove the experimental designation. *Id.* As part of that discussion, Reali stated that

it is important to remember that the current code we have, which is a T code [Category III code] is not an experimental code. It is a tracking code. What we hope to do in the near term is work with payers to get that tracking code covered. Over time, as we evolve on this strategy and we penetrate the market, a

decision will be made when we would apply for a category one code. But until we are successful in all parts of our strategy relative to payer acceptance and spine society endorsements and continued publications, we will not submit for a category one code.

Id. (emphasis in original).

c. Reimbursement Guide and Template

The “Defendants also developed and distributed to surgeons a ‘Reimbursement Guide,’ dated January 1, 2009 through June 30, 2009.” *Id.* ¶ 35. The guide included a number of CPT codes that it stated “may be appropriate during an AxiaLIF procedure.” *Id.* On the last page of the guide, it stated that “AxiaLIF has been assigned a Category III CPT billing code,” and “acknowledge[d] that payors may deny claims submitted under the Category III CPT code.” *Id.* The guide then “direct[ed] physicians to use alternate codes to secure reimbursement.” *Id.*

A surgeon named Dr. William Tobler also “created a template that discussed exactly how to code the procedure as an anterior procedure so that the surgeons could get reimbursed.” *Id.* ¶ 63. The template further contained “suggested post-operation notes so the insurance companies would not view the procedure as an AxiaLIF procedure and deny reimbursement.” *Id.*⁸

d. National Meeting

At an annual meeting held by TranS1 in January 2009, “the Company continued to promote use of the anterior CPT code, despite the fact that the Category III code had already been assigned to AxiaLIF.” *Id.* ¶¶ 37, 64, 115.⁹ Defendant Randall attended the meeting. *Id.*

⁸ The SAC, during this discussion of the template, also include an allegation that a former District Sales Manager for TranS1 was instructed to tell surgeons: “I can’t give you direct advice on how to code, but here is what I’ve heard other people are doing.” *Id.* The SAC does not state who instructed the Sales Manager to use that instruction.

⁹ The SAC, in the middle of a paragraph detailing allegations about the January 2009 meeting, states that a confidential witness “said the official company line was to tell surgeons, ‘We have a [Category III CPT code], but here’s how other guys are coding it.’” *Id.* ¶ 64. The SAC does not state whether this “official company line” was stated at the meeting nor whether Defendant Randall, who attended that meeting, was the one who made the statement.

e. Public Disclosures

On March 13, 2009, TranS1 filed an annual report on Form 10-K with the Securities and Exchange Commission (“SEC”). *Id.* ¶ 70. Defendants Randall, Luetkemeyer, and Slattery signed the report, and Randall and Luetkemeyer made signed certifications stating that the financial information in the Form 10-K was accurate. *Id.* The Form 10-K stated, in part,

Effective January 1, 2009, AxiaLIF has a dedicated Category III CPT code Unlike Category I CPT codes, Category III codes do not have a set value which physicians use to set their charge for a particular code. Additionally, some payors view Category III codes as “investigational” or “experimental” and may not reimburse them. However, AxiaLIF adoption continues to grow and unlike many new or novel procedures, AxiaLIF is an access variation on the current standard of care (spinal fusion). As the availability of peer-reviewed research continues to grow, we will diligently work with the private payor community to ensure continued patient access to the procedure. Furthermore, AxiaLIF is only one of up to 10 different CPT codes physicians may submit to capture the entirety of a spinal fusion procedure lessening the impact should payment for our code be initially denied.

Id. ¶ 71; *see also id.* ¶ 99 (outlining another public disclosure, this one signed by Defendants Slattery and Reali, that uses similar language). The plaintiff alleges that this excerpt was false because it failed to disclose the alleged scheme, the scheme’s illegality, and that the scheme created a “substantial risk that Trans1 would encounter regulatory scrutiny.” *Id.* ¶ 72. The SAC repeats this pattern several times, noting TranS1’s public filings with the SEC and stating that the filings failed to disclose the scheme, its illegality, and the increased risk of regulatory scrutiny.

See generally id. ¶¶ 75-106.

f. Randall’s Stock Dealings

Between May 26 and 27, 2010, “Defendant Randall disposed of a massive 100,000 shares of Company stock at inflated prices. He sold an additional 20,000 shares of stock at inflated prices on August 17, 2011.” *Id.* ¶ 116. Randall’s stock transactions occurred only during the

Class Period (between February 23, 2009, and October 17, 2011). *See id.* ¶¶ 1, 116. The SAC does not make further allegations concerning the other defendants' stock transactions.

g. The Plaintiff's Claims

The SAC alleges that the defendants must have known of the "improper reimbursement scheme" because (1) the defendants "made numerous statements regarding the challenges incurred because of the Category III designation for AxiaLIF;" (2) "Amy Connors, the head of Trans1's reimbursement committee, made a number of presentations to management and the Board of Directors regarding reimbursement issues in light of the AMA's Category III designation;" and (3) "the Company employed less than 130 individuals." *See id.* ¶¶ 113-14. The plaintiff has brought claims against the defendants (1) under Section 10(b) of the Exchange Act, 15 U.S.C. § 78k(b), and Rule 10b-5, and (2) under Section 20(a) of the Exchange Act. *See SAC [DE-55]* at ¶¶ 128-44.

II. LEGAL STANDARD

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint, not to resolve conflicts of fact or to decide the merits of the action. *Edwards v. City of Goldsboro*, 178 F.3d 231, 243-44 (4th Cir. 1999). In considering a motion to dismiss, the court assumes the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000). However, the "[f]actual allegations must be enough to raise a right to relief above the speculative level' and have 'enough facts to state a claim to relief that is plausible on its face.'" *Wahi v. Charleston Area Med. Ctr., Inc.*, 562 F.3d 599, 615 n.26 (4th Cir. 2009) (alteration in original) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007)). "[A] plaintiff's

obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.”

Twombly, 550 U.S. at 555 (second alteration in original) (citations omitted). Moreover, a court “need not accept the legal conclusions drawn from the facts” nor “accept as true unwarranted inferences, unreasonable conclusions, or arguments.” *E. Shore Mkts.*, 213 F.3d at 180. The court may consider “documents incorporated into the complaint by reference, and matters of which a court may take judicial notice” when deciding a Rule 12(b)(6) motion. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

III. DISCUSSION

In order to state a claim under Section 10(b) and Rule 10b-5, a plaintiff must allege “(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 157 (2008). Moreover, a plaintiff must plead with particularity the circumstance constituting fraud. *See* Fed. R. Civ. P. 9(b). This particularity requires that a plaintiff, “at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.” *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (internal quotation marks omitted). In other words, the plaintiff must state the “who, what, when, where, and how of the alleged fraud.” *Id.* (internal quotation marks omitted).

Under the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4 *et seq.*, a complaint alleging securities fraud must also “state with particularity facts giving rise to a *strong* inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2)(A)

(emphasis added). This strong inference does not merely require an inference from which “a reasonable person could infer that the defendant acted with the required intent,” but instead requires a “powerful or cogent” inference. *Tellabs*, 551 U.S. at 323. Furthermore, “when the facts as a whole more plausibly suggest that the defendant acted innocently—or even negligently—rather than with intent or severe recklessness, the action must be dismissed.”

Cozzarelli v. Inspire Pharm. Inc., 549 F.3d 618, 624 (4th Cir. 2008).

Further rules apply where a complaint alleges fraud by omission. For an omission to be actionable under securities law, it must “create an impression of a state of affairs that differs in a material way from the one that actually exists.” *Iron Workers Local 16 Pension Fund v. Hilb Rogal & Hobbs Co.*, 432 F. Supp. 2d 571, 584 (E.D. Va. 2006) (citing *Phillips v. LCI Int'l, Inc.*, 190 F.3d 609, 613 (4th Cir. 1999)). “[I]t bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information.” *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1321 (2011). Instead, “[d]isclosure is required under these provisions only when necessary ‘to make . . . statements made, in the light of the circumstances under which they were made, not misleading.’” *Id.* (quoting 17 C.F.R. § 240.10b-5(b)). “Even with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market.” *Id.* at 1322. That said, if a company “puts the topic of the cause of its financial success at issue, then it is ‘obligated to disclose information concerning the source of its success, since reasonable investors would find that such information would significantly alter the mix of available information.’” *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400-01 (S.D.N.Y. 2005) (citing *In re Providian Fin. Corp. Sec. Litig.*, 152 F. Supp. 2d 814, 824-25 (E.D. Pa. 2001)).

a. The SAC fails to allege a material misrepresentation or omission by the individual defendants.

The court has reviewed the SAC in great detail and cannot find a material misrepresentation or omission made by any of the individual defendants. The SAC does not contain sufficient factual allegations to show (1) that the individual defendants knew TranS1’s reimbursement practices were illegal, or (2) that the individual defendants encouraged surgeons to omit the Category III CTP code.

i. The individual defendants did know that TranS1’s reimbursement practices were illegal.

The plaintiff’s primary contention is that the defendants failed to disclose the illegality of TranS1’s reimbursement practices. Indeed, the plaintiff accuses the defendants of being “masters of the partial truth” in that the defendants (1) disclosed the CPT code change and the elements of TranS1’s reimbursement practices, but allegedly (2) failed to disclose the illegality of those reimbursement practices. *See Memorandum of Law in Opposition to Defendants’ Motion to Dismiss Plaintiff’s SAC [DE-66]* at 13. The SAC rises and falls on this argument. If the SAC sufficiently alleges that the defendants knew of and failed to disclose the illegality of TranS1’s reimbursement practices, the SAC will likely survive. If, however, the SAC’s allegations do not show that the defendants knew TranS1’s reimbursement practices were illegal—even if they otherwise knew the extent of TranS1’s practices—then the defendants never had a duty to disclose the illegality of those practices. The SAC fails because at no point does it evince that the defendants knew that TranS1’s reimbursement practices were illegal.

First, as a general rule, “securities law does not require that [a company] accuse itself of wrongdoing,” nor does it impose “a duty to disclose illegal and illicit activities.” *Hilb Rogal*, 432 F. Supp. 2d at 585, 587. Indeed, “Rule 10b-5 was not intended to provide shareholders with an avenue for relief against executives for alleged illegal practices or corporate

mismanagement” *Id.* at 586-87 (quoting *Galati v. Commerce Bancorp, Inc.*, No. Civ. 04-3252(RBK), 2005 WL 3797764, at *8 (D.N.J. Nov. 7, 2005)). Thus, even if a company is aware of the illegality of its practices, it is generally not under a duty to disclose that illegality. Only when a party “voluntarily discloses material facts in connection with a securities transaction” does that party “assume[] a duty to speak fully and truthfully on those subjects.” *Chamberlain v. Reddy Ice Holdings, Inc.*, 757 F. Supp. 2d 683, 707 (E.D. Mich. 2010). That is, if a party speaks of its reimbursement practices knowing that they are illegal, but does not fully disclose the illegality of those practices, the party has violated its duty to speak fully and truthfully. Here, however, there are no allegations in the SAC that any of the defendants knew TranS1’s reimbursement practices were illegal.

Second, securities law requires “‘disclosure of information *that is not otherwise* in the public domain,’ not information that has already been publicly—indeed, officially—disclosed by the company.” *Hillson Partners Ltd. P’ship v. Adage, Inc.*, 42 F.3d 204, 212 (4th Cir. 1994) (quoting *Sailors v. N. States Power Co.*, 4 F.3d 610, 613 (8th Cir. 1993)) (emphasis in original). The allegations of the SAC show that TranS1 otherwise disclosed its reimbursement practices to the public in conference calls and public filings:

- (1) AxiaLIF had received a Category III CPT code designation. *See* SAC [DE-55] ¶¶ 69, 71, 74, 88, 99.
- (2) TranS1 had set up an 800 number and call-in resource center to help surgeons with billing. *Id.* ¶¶ 69, 74.
- (3) TranS1 had “reimbursement specialists in the field to work with [its] surgeon customers and their billing specialists, to help them determine the appropriate coding for the fusion procedures they are performing.” *Id.* ¶ 74. These specialists worked with surgeons regarding the coding sequence for spinal fusion procedures. *Id.* The specialists would also meet with surgeons regarding billing before the surgeons performed operations with AxiaLIF. *Id.*
- (4) TranS1 had published a coding guide. *Id.*

Furthermore, the court has previously taken judicial notice of TranS1’s public filings, which filings show that it disclosed the increased risk of regulatory scrutiny and litigation. *See, e.g.*, Form 10-K for Fiscal Year 2008 [DE-33-3] at 39-41 (“This risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.”); Form 10-K for Fiscal Year 2009 [DE-33-11] at 51-52; Form 10-K for Fiscal Year 2010 [DE-33-19] at 29-31. Those heightened risks included risks associated with “promotional materials, labeling, training or other marking or educational activities” *See* Form 10-K for Fiscal Year 2010 [DE-33-19] at 30.

Unless the plaintiff is contending that the defendants needed to disclose each and every aspect of TranS1’s reimbursement practices, down to the most minute detail, the court does not see how the defendants failed to sufficiently disclose TranS1’s reimbursement practices. Moreover, the court does not find that the defendants were required to provide that degree of disclosure. Instead, “[d]isclosure is required under these provisions only when necessary ‘to make . . . statements made, in the light of the circumstances under which they were made, not misleading.’” *Siracusano*, 131 S. Ct. at 1321 (quoting 17 C.F.R. § 240.10b-5(b)). No further disclosure was required because the defendants’ statements were not misleading under the circumstances they were made.

The plaintiff claims that “[t]he Complaint alleges that Defendants were fully aware of the reimbursement scheme and knew about the rampant violations of the very statutes they claimed to have attempted to uphold.” *See* Mem. Opp. Mot. Dismiss SAC [DE-66] at 15. But the plaintiff does not cite a single paragraph of the SAC that shows the defendants knew TranS1’s reimbursement practices were illegal, nor can the court find any such allegation. The

plaintiff attempts several times in its Memorandum in Opposition [DE-66] to prop up its complaint by arguing that the defendants “knew about or recklessly disregarded, practices to encourage surgeons to illegally dupe insurance companies,” but these statements are merely conclusory and are unsupported by any specific allegations. *Id.* at 14.

The defendants argue that *Indiana State District Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935 (6th Cir. 2009), is analogous to the present case and should guide this court’s decision. In *Omnicare*, the defendant corporation made public statements asserting legal compliance with applicable federal standards. *Id.* at 941 (“Omnicare’s policy is to comply with all applicable federal and state laws and regulations. To the best of our knowledge, our purchases of pharmaceuticals comply with all applicable laws and regulations and are consistent with Omnicare’s goal of providing appropriate pharmaceutical care cost-effectively for the seniors we serve.”). However, the corporation’s practices were in fact illegal. *See id.* Despite the disconnect between the compliance statements and the company’s practices, the *Omnicare* court found the complaint failed to sufficiently allege that any of the defendants knew the company’s practices were illegal. *See id.* at 945-46.

In contrast, the plaintiff argues that *Chamberlain v. Reddy Ice Holdings*, should guide. In *Chamberlain*, the court distinguished its case from *Omnicare*, noting that the complaint adequately alleged that the defendants in *Chamberlain* (1) knew that their activities were illegal, (2) still entered into those activities, and (3) “made express representations to the contrary in multiple public filings” while giving other reasons for their market share and earnings. 757 F. Supp. 2d at 709.

The present case is more analogous to *Omnicare*. The SAC contains no allegations that the defendants (1) knew TranS1’s reimbursement practices were illegal and (2) made express

representation to the contrary. Moreover, the court cannot find affirmative statements made by any of the individual defendants regarding compliance with particular legal requirements and the plaintiff has not cited to any in its briefings. Instead, as in *Omnicare*, the SAC has a dearth of factual allegations supporting the claim that the individual defendants knew TranS1's reimbursement practices were illegal. *See* 583 F.3d at 945-47. The other cases cited by the plaintiff in support of its position are similarly unavailing.¹⁰

The SAC fails to state a claim (1) because it does not allege that the defendants knew TranS1's reimbursement practices were illegal, and (2) because it does not otherwise show how the defendants' public disclosures were materially misleading. The SAC can be dismissed based on this alone.

ii. The defendants did not encourage surgeons to omit the Category III CPT code.

The SAC does not contain any factual allegations showing that the individual defendants encouraged the omission of the Category III CPT code, nor that TranS1's reimbursement practices encouraged surgeons to omit the code.¹¹ Instead, the SAC shows that TranS1 openly

¹⁰ *See In re Pozen Sec. Litig.*, 386 F. Supp. 2d 641, 645-46 (M.D.N.C. 2005) (finding that a drug maker made affirmative statements that its drug would be approved by the Food and Drug Administration ["FDA"] knowing full well that its drug had not been passing the tests that the FDA and the drug maker had agreed the drug would need to pass in order to be approved); *Meyer v. Jinkosolar Holdings Co., Ltd.*, 761 F.3d 245, 251 (2d Cir. 2014) (holding that failure to disclose instances of non-compliance "could be found by a trier of fact to be an omission that renders misleading the comforting statements in the prospectus about compliance measures"). The defendant in *Jinkosolar* had a duty to disclose the "ongoing and serious pollution violations," not because of the violations themselves, but because the defendant had made affirmative statements indicating compliance with regulations knowing that it was not in compliance. *See* 761 F.3d at 251.

¹¹ The paragraphs referencing the *qui tam* complaint do contain several allegations to this effect; however, those allegations are incomplete. *See* SAC [DE-55] ¶¶ 39-46. The only non-conclusory allegations in this section that might apply to the individual defendants are found in ¶ 43: "Defendants coached hospitals and physicians to omit all references to the T-Code assignment and to instead improperly code AxialIF as one of the Medicare reimbursable anterior and/or posterior interbody fusion procedures." However, this allegation does not state which of the individual defendants provided the coaching nor when. Instead, even if the individual defendants were aware of TranS1's reimbursement

admitted that AxiaLIF had received a Category III CPT code and promoted inclusion of the code, albeit in a certain billing code order. Specifically, the SAC shows the following.

- (1) Conners's presentations to surgeons would not teach them to omit the Category III CPT code, but rather how to "bury" the code in the "bottom part of the reimbursement request so that insurance companies might overlook it." *See* SAC [DE-55] ¶¶ 51, 54.¹²
- (2) Defendant Randall, during the February 23, 2009 conference call, stated that "a portion of our surgeon fee migrated from an unlisted code to a category three CPT tracking code in January 2009." *Id.* ¶ 69. In another call on April 27, 2009, Randall again said that AxiaLIF had received a Category III CPT code. *Id.* ¶ 74.
- (3) During a May 24, 2010 conference call, Defendant Reali stated that AxiaLIF had received a Category III code and that TranS1 would not be submitting for a Category I code. *Id.* ¶ 88.
- (4) The reimbursement guide and template stated that "AxiaLIF has been assigned a Category III CPT billing code," and acknowledged that "payors may deny claims submitted under the Category III CPT code." *Id.* ¶ 35.¹³
- (5) TranS1's public filings stated that "AxiaLIF has a dedicated Category III CPT code Unlike Category I CPT codes, Category III codes do not have a set value which physicians use to set their charge for a particular code. Additionally, some

practices, the factual allegations of the SAC show that those practices did not encourage the omission of the Category III CPT code.

¹² The SAC contains no specific allegations concerning *what* Conners presented to TranS1's board about the reimbursement issues.

¹³ The court addresses the guide's direction to use alternate codes on the following page of this order.

payors view Category III codes as ‘investigational’ or ‘experimental’ and may not reimburse them.” *Id.* ¶ 71; *see also id.* ¶ 99.

The plaintiff argues in his brief that it was inappropriate for the defendants to advise surgeons to use multiple codes when billing a procedure. *See Mem. Opp. Mot. Dismiss SAC* [DE-66] at 16. The SAC, however, does not allege that such a practice was improper. Indeed, even the settlement agreement between TranS1 and the government does not indicate that using multiple codes, in and of itself, is inappropriate. *See Settlement Agreement* [DE-46-1] at 2-3, ¶ D. Moreover, the SAC does not allege that the defendants knew that using multiple codes was inappropriate. Even if billing with multiple codes was inappropriate, the SAC shows that the defendants fully disclosed that TranS1 encouraged billing for AxiaLIF with multiple CPT codes. *See SAC* [DE-55] ¶¶ 71, 74 (quoting Defendant Randall discussing the “coding sequence,” and quoting the 10-K public filing that discusses AxiaLIF being one of “up to 10 different CPT codes physicians may submit to capture the *entirety* of a spinal fusion procedure” (emphasis added)). Based on the allegations of the SAC, the court cannot say that using multiple codes for a single procedure was inappropriate, much less that the individual defendants knew such a practice was inappropriate.

The two allegations that come closest to, but fall short of, showing that the individual defendants encouraged omission of the Category III CPT code are (1) that Defendant Randall attended a meeting in January 2009 where “the Company continued to promote use of the anterior CPT code, despite the fact that the Category III code had already been assigned to AxiaLIF;” and (2) that TranS1 had created a billing guide directing “physicians to use alternate codes to secure reimbursement” if the Category III CPT code was rejected, and that the billing guide had been “blessed by everyone.” *Id.* ¶¶ 37, 64, 115 (meeting), 35, 74 (billing guide). These

allegations alone are insufficient to show that TranS1 was actively encouraging surgeons to omit the Category III code.

First, as to the meeting attended by Defendant Randall, the allegations discussing the meeting do not state that Defendant Randall himself “promote[d] use of the anterior CPT code, despite the fact that the Category III code had been assigned to AxiaLIF.” *Id.* ¶¶ 37, 64. Indeed, the SAC does not say who made the statement, nor does the SAC allege that Defendant Randall acknowledged it, approved it, endorsed it, or even heard it.

Second, as to the billing guide, the SAC does not allege which of the defendants, if any, actually developed and distributed the guide. The most the SAC alleges as to the defendants’ participation is Defendant Randall’s lone statement that it had been “blessed by everyone.” *Id.* ¶ 74. However, even that statement does not say who “everyone” is, nor what is meant by “blessed.” More importantly, the allegations do not show that the defendants knew of the instruction to use alternate codes, which was included at the very end of the guide after the initial instruction to include the Category III CPT code.

Third, the SAC does not contain allegations stating that the defendants otherwise encouraged surgeons to omit the Category III CPT code. Instead, the SAC shows that TranS1’s materials and public disclosures openly admitted that AxiaLIF had received a Category III code. These two allegations alone do not sufficiently plead with particularity the circumstances constituting fraud. *See Fed. R. Civ. P. 9(b); see also Kellogg Brown & Root, 525 F.3d at 379.*¹⁴ Thus, the SAC fails to allege a material misrepresentation by the defendants.

¹⁴ The SAC also alleges that TranS1 instructed distributors to use an anterior procedure billing code. *See SAC [DE-55] ¶¶ 56-57.* However, these allegations do not say who at TranS1 gave these instructions, when, or to whom. Similarly, even where there are specific instances of doctors using the incorrect code “per Trans1’s instruction,” those instances do not say who gave the instructions, let alone that the individual defendants gave the instructions. *See id.* ¶ 44.

b. The SAC fails to allege a strong inference of scienter.

The SAC does not allege when and how the individual defendants knew or recklessly failed to know that their disclosures and statements were false or misleading, much less make a “powerful or cogent” inference of the defendants’ scienter. *Tellabs*, 551 U.S. at 323. The plaintiff argues that the SAC sufficiently pleads a strong inference of scienter, specifically recklessness, for the following reasons: (1) AxiaLIF was very significant to TranS1’s viability, (2) the defendants knowingly violated an unambiguous AMA directive, (3) the Confidential Witness (“CW”) statements show scienter, (4) the *qui tam* action and the Department of Health and Human Services investigation fortify the inference of scienter, and (5) the defendants do not offer a competing inference of scienter. These arguments all fail.

First, the plaintiff argues that AxiaLIF’s significance shows that the defendants had to know the full extent of TranS1’s reimbursement practices. This argument misses the mark. The real question is whether the defendants knew that their public disclosures were misleading. Even if the court were to assume that the defendants had full knowledge of TranS1’s reimbursement practices, the court has previously discussed that the SAC (1) fails to allege that the defendants knew the practices were illegal, and (2) shows that the defendants adequately disclosed TranS1’s reimbursement practices in their public disclosures and statements. The SAC does not show an inference, much less a compelling one, that the defendants knew their public disclosures were misleading.

Second, the plaintiff argues that the defendants knowingly violated an unambiguous AMA directive. While the plaintiff argues that the defendants “*believed it was appropriate to bill for AxiaLIF as a non-Category III procedure*,” *see* Mem. Opp. Mot. Dismiss SAC [DE-66] at 26 (emphasis in original), the SAC does not support this claim. Instead, the SAC shows (1) that the

defendants openly admitted that AxialLIF had received a Category III CPT code, (2) that the reimbursement guide noted that AxialLIF had received the Category III code, and (3) that the defendants did not encourage omission of the Category III CPT code. The SAC does not show that the individual defendants knowingly violated the AMA directive.

Third, the CW statements face the same problems previously discussed. The CW statements might, at best, indicate that the individual defendants knew the full extent of TranS1's reimbursement practices. However, the CW statements do not show that the individual defendants knew that their public statements and TranS1's public disclosures were misleading. That is what the SAC must show in order to adequately plead scienter.¹⁵

¹⁵ The plaintiff's argument concerning the CW statements appears to be an attempt to supplement the SAC through the brief. The SAC must stand or fall on its own. Even so, the plaintiff's argument concerning the CW statements contain arguments that are not supported by the SAC. The argument states, in part, that

the Individual Defendants: (a) were aware of the Category III designation; (b) directed Tobler to create a Reimbursement Template to show surgeons *how to avoid the Category III code*; (c) created a Reimbursement Committee, head[ed] by Amy Conner, designed to train surgeons to bypass the Category III code; (d) drafted and distributed a Reimbursement Guide that *explicitly advised surgeons to use alternative inapplicable coding* to avoid having their claims for AxialLIF procedures denied; (e) instructed numerous distributors to *circumvent the mandatory Category III code*; and (f) were present at *various meetings* at which the illegal reimbursement scheme was detailed and discussed.

Mem. Opp. Mot. Dismiss SAC [DE-66] at 26 (emphasis added). The emphasized portions of this excerpt are either not included in the SAC or are misstatements of what is contained in the SAC.

First, none of the allegations concerning Tobler's creation of the template state that it showed surgeons to avoid the Category III code, but instead state that the template guided surgeons in how to receive reimbursement. *See SAC [DE-55] ¶¶ 36, 63.*

Second, the SAC alleges that the reimbursement acknowledged that "AxialLIF ha[d] been assigned a Category III CPT billing code" and that "payors may deny claims submitted under the Category III CPT code." *Id.* ¶ 35. While the SAC does allege that the guide "directs physicians to use alternate codes to secure reimbursement," it does not allege that the guide directed physicians to omit the code and does not indicate whether those alternate codes are to be used instead of the Category III code or in addition to the Category III code. *Id.* The latter is more consistent with the other allegations of the SAC.

Third, the SAC does not contain allegations that the individual defendants specifically instructed distributors to circumvent the mandatory Category III code. Any allegations to that effect are conclusory. *See, e.g., id.* ¶ 43 ("Since 2009, Defendants coached hospitals and

Fourth, the *qui tam* complaint does not support a strong inference of scienter. TranS1 expressly denied the allegations of the *qui tam* complaint in the settlement agreement and did not admit liability. *See* Settlement Agreement [DE-46-1] at 3, ¶ E.

Fifth, the defendants do offer a competing inference of scienter. The defendants argue that they disclosed TranS1's reimbursement practices in their public statements and in TranS1's public filings. The SAC supports that argument.

In addition to these arguments, the plaintiff argues that the SAC establishes, at a minimum, corporate scienter. *See* Mem. Opp. Mot. Dismiss SAC [DE-66] at 24. Even if the court were to find, *arguendo*, that the SAC adequately pleads corporate scienter, corporate scienter is not presently relevant as this action has been stayed against TranS1. *See* Order of November 20, 2014 [DE-69]. Furthermore, even if, *arguendo*, the plaintiff had sufficiently pled corporate scienter, the plaintiff again misconstrues what TranS1 and the individual defendants needed to know. The defendants did not need to know about the reimbursement practices, but rather that their statements regarding the reimbursement practices were *misleading*. The SAC does not sufficiently allege scienter, much less a compelling inference of scienter.¹⁶

physicians to omit all references to the T-Code assignment and to instead improperly code AxialLIF as one of the Medicare reimbursable anterior and/or posterior interbody fusion procedures.”). Such allegations do not contain the necessary who, when, and where of the alleged fraud, particularly not as to the individual defendants. Instead, the factual allegations of the SAC show that TranS1 acknowledged the Category III code and did not instruct providers to omit the code.

Fourth, the only meeting referenced in the SAC was the January 2009 meeting. *Id.* ¶¶ 37, 64, 115. The only allegations as to that meeting are that “the Company continued to promote use of the anterior CPT code,” not that the company promoted omission of the Category III CPT code. *See id.* Furthermore, while a 2008 meeting is mentioned, the Category III CPT code was not effective at that time. *See id.* ¶¶ 30, 64.

¹⁶ Because the defendants’ knowledge of TranS1’s reimbursement practices does not matter to the question of scienter, any impact that the individual defendants’ corporate positions had on their knowledge is irrelevant, even independent of the Fourth Circuit’s holding that corporate position alone cannot establish intent or recklessness. *See Yates v. Mortg. & Equity, LLC*, 733 F.3d 874, 890 (4th Cir. 2014).

Additionally, the stock sales in the present case do not provide any inference of scienter let alone a strong inference. First, the SAC shows that only Defendant Randall sold some of his holdings during the relevant period. The SAC contains no allegations that the other three individual defendants sold off stock holdings. Indeed, the court has taken judicial notice that Defendant Slattery *increased* his holdings during the relevant period. Second, the percentage of holdings sold by Defendant Randall is insufficient to establish scienter. *See Proter v. Medifast, Inc.*, No. GLR-11-720, 2013 WL 1316034, at *21 n.20 (D. Md. Mar. 28, 2013) (citing numerous cases where sales of holdings, even up to forty-two percent of holdings, did not support an inference of scienter).

Finally, the court considers instructive the contrast between the lack of scienter allegations in the present case and the straightforward scienter allegation of *United States Securities and Exchange Commission v. Staples*, No. 3:13-CV-2575-JMC, 2014 WL 4792115 (D.S.C. Sept. 24, 2014). In *Staples*, the government simply alleged that the defendants “were aware that each Program participant had relinquished all ownership rights in the bonds and *despite knowing this*, they falsely represented that they were entitled to redeem the bonds pursuant to the survivor’s option because the deceased were ‘owners’ of the bonds.” *Id.* at *6-7 (emphasis added). The *Staples* court found that lone allegation sufficient to support a finding of scienter. Nowhere in the SAC does the plaintiff approach making a single allegation or multiple allegations in concert showing that the individual defendants knew they were making material misrepresentations or omissions.

The plaintiff has had three opportunities to submit a complaint that meets the requirements set forth herein. He has failed to do so. Because the SAC fails to allege a material misrepresentation or omission by the individual defendants, and because the SAC fails to allege

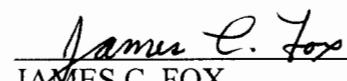
a strong inference of scienter that the defendants knew they were making material misrepresentations or omissions, the SAC will be dismissed.

IV. CONCLUSION

The court orders that the stay entered by its Order of November 20, 2014 [DE-69] is hereby LIFTED. The defendants' Request for Judicial Notice [DE-60] is ALLOWED. The defendants' Motion to Dismiss Plaintiff's Second Amended Complaint [DE-63] is ALLOWED. The plaintiff's claims against the individual defendants are hereby DISMISSED WITH PREJUDICE. The stay of the plaintiff's claims against Defendant TranS1 remains in effect; however, the Clerk of Court is DIRECTED to administratively close this case from the active docket, subject to the same being reopened by any party upon the resolution of TranS1's bankruptcy action in the Bankruptcy Court for the District of Delaware, or otherwise upon good cause shown.

SO ORDERED.

This, the 14 day of May, 2015.



JAMES C. FOX
Senior United States District Judge